Exhibit E

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: BARD IVC FILTERS PRODUCTS)
LIABILITY LITIGATION) MD No.: 02641
_____)

DO NOT DISCLOSE - SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

CONTINUED VIDEOTAPED DEPOSITION OF CHAD MICHAEL MODRA

Phoenix, Arizona
January 20, 2016
9:01 a.m.

REPORTED BY:
Robin L. B. Osterode, RPR, CSR
AZ Certified Reporter No. 50695

a good idea?

MR. NORTH: Objection to the form.

THE WITNESS: Those events for the filter is typically the events are reported at either explant -- so whether we went back or not, I don't believe it was necessary.

BY MR. LOPEZ:

Q. I mean, aren't you concerned that maybe a lot of the early reports for the Recovery and the G2 were reported by your company as malfunctions to FDA, and, in fact, they involved deaths and other serious injuries, like open heart surgery --

MR. NORTH: Objection --

BY MR. LOPEZ:

Q. -- aren't you concerned about that?

MR. NORTH: Objection to the form.

THE WITNESS: Obviously, I'm concerned very much about injuries.

BY MR. LOPEZ:

Q. Okay. So why not do for those people what you've done for the people that got reported, you know, after 2013 or --

MR. NORTH: Objection to the form.

THE WITNESS: As far as incorrectly checking the wrong box on the report to FDA, that

didn't change anything related to the investigation that we did, the trending that we did, related to the devices. In fact, I looked back and the rates for those key events, fracture, migration, tilt, before and after the retrospective reviews of these complaint files, didn't change, which -- which confirmed that the designation was originally there.

BY MR. LOPEZ:

Q. Yeah, but, sir, at FDA on the -- the FDA is the MAUDE database. Right? In other words --

A. Yes.

Q. -- that put things -- so the MAUDE, aren't you concerned that the MAUDE database has got 30 percent malfunctions that should say 30 percent serious injuries from reports that came to your company over a two-year period?

A. It's concerning, because I want to make sure that we're reporting things to the level of expectation.

Q. Right. And shouldn't you have that same concern for all of the reporting that preceded that 30 percent failure rate?

A. The reporting, whether or not it was reported, is independent of what we did to trend it, track it, take corrective action or not.

injury, and go back and make sure that all reports dealing with all filters prior to those thousand are now corrected and designated as serious injury reports?

A. And --

Q. Don't you think you should do that?

MR. NORTH: Objection to the form.

THE WITNESS: I responded here, and I didn't, because I didn't think --

BY MR. LOPEZ:

Q. So you don't think you should?

MR. NORTH: Objection, he's --

MR. LOPEZ: I know, but I'm asking a real specific question and he wants to give me some kind of answer that has nothing to do with the question.

THE WITNESS: Well, I wanted to explain my answer.

BY MR. LOPEZ:

Q. No, but the question is -- but the question is, don't you think you should go back and audit the same database or files that predate those thousand, to see if you have inaccurately categorized any number of those at that same percentage or even greater as being not serious injury when they should have been categorized as serious injury?

A. Well, that's an assumption that it would have been greater.

Q. Exactly. But that's why don't you think you should go back and look?

A. No, we went back a number of years --

Q. Don't you think you should go back and look is all I'm asking you?

MR. NORTH: Objection to the form. Argumentative.

THE WITNESS: No. Because of the fact that the key severe -- severity, serious injury and death-related complaints had been reported originally that way to the FDA.

BY MR. LOPEZ:

Q. Well, we don't -- we don't know that because you haven't audited them. You haven't done an audit of those?

MR. NORTH: Objection to the form.

THE WITNESS: Well, I look at the rates --

BY MR. LOPEZ:

Q. No, but you --

A. -- before and after the retrospective review on those key failure modes, and there was no difference between them, which means there was no difference in effect in any of those records.

Q. I know, but -- you "believe we do"?

A. Yeah, because we've double-checked it internally, and we've had others look at it outside of our organization, internal to Bard, but we haven't had an outside person review yet --

Q. Okay.

A. -- which is one more step we want to do.

Q. Okay. Let me see if I understand what you just said. So have you taken this same body of evidence, these MDRs, these approximate thousand MDRs --

A. Uh-huh.

Q. -- where there were approximately 300 that were reported as malfunctions, and have now looked to see if you have trended those to include those 300 as serious injuries?

A. They were --

Q. Sir, have you done that?

A. No, because they were trended before.

Q. Okay.

A. There would be no value to trend them only as serious injury. You want to trend them for the reported failure mode. So you don't just trend it on a serious injury and then -- and do it that way. You have to have greater granularity to it, so we trend

it based on the reported event code, stuck in delivery system, fracture, movement, whatever it might be.

Q. Tilting, perforation?

A. Tilting, perforation.

Q. Pleural effusion?

A. Right. So independent of its reporting, we would look at it based on an event, not so much reporting.

Q. Okay. My question is, have you gone back and looked at your trending of those 300 misreported events and have determined that your company, in fact, internally had tracked and trended those 300 as injuries or failure modes?

A. No, I did it based on the reported event, and verified that there wasn't any impact; there was no difference in the number reported for those injuries that you mentioned, the fracture, migration, tilt, perforation.

Q. Okay. I'm not understanding that, because I thought you said that irrespective of how you may report to FDA, let's talk about these 300, internally within the company, you would have picked up those 300, and they would have become part of your trending and tracking information?

A. They were -- they were always part of the trending and tracking; I'm sorry if I was -- wasn't clear.

Q. So who does that and how does that come about?

A. It's part of our field assurance and post-market surveillance. Those events are placed into validated Excel spreadsheets and tracked and trended on a --

Q. So --

A. -- monthly basis.

Q. So internally, the company is keeping track of injuries and how it's trended, and how many there are, what categories they can go in. That's all being done internally. Right?

A. Correct.

Q. And -- but as far as the way those are being reported to a database, meaning the FDA, they're not being reported as the same way you're trending them, because you're reporting them as malfunctions and not failure modes or serious injuries?

A. Well, now they've -- they've all been submitted.

Q. They've been fixed now. Right?